

## INFORMATION DISCLOSURE

~~8~~ STATEMENT BY APPLICANT

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of

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<b>Application Number</b>	10/594,373
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<b>Filing Date</b>	September 27, 2006
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<b>First Named Inventor</b>	Alan Meehan
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Group Art Unit	--
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Examiner Name --

Attorney Docket Number	21438P
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[illegible][illegible]Examiner  
Signature

/Umamaheswari Ramachandran/

Date  
Considered

12/10/2009

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NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
/U.R./	AA	Roehrborn et al., Urology, Vol. 62 (2003), pp. 894-899, "Effects of finasteride on serum testosterone and body mass index in men with benign prostatic hyperplasia"
	AB	McConnell et al., J. Clin. Endocrinol. Metab., Vol. 74 (1992), pp. 505-508, "Finasteride, an inhibitor of 5alpha-reductase, suppresses prostatic dihydrotestosterone in men with benign prostatic hyperplasia"
	AC	Page et al., J. Clin. Endocrinol. Metab., Vol. 90 (2005), pp. 1502-1510, "Exogenous testosterone (T) alone or with finasteride increases physical performance, grip strength, and lean body mass in older men with low serum T"
	AD	Amory et al., J. Clin. Endocrinol. Metab., Vol. 89 (2004), pp. 503-510, "Exogenous testosterone or testosterone with finasteride increases bone mineral density in older men with low serum testosterone"
	AE	Gormley et al., N. Eng. J. Med., Vol. 327 (1992), pp. 1185-1191, "The effect of finasteride in men with benign prostatic hyperplasia"
	AF	Marin et al., Obesity Research, Vol. 1 (1993), pp. 245-251, "Androgen treatment of abdominally obese men"
	AG	Boyanov et al., The Aging Male, Vol. 6 (2003), pp. 1-7, "Testosterone supplementation in men with type 2 diabetes, visceral obesity and partial androgen deficiency"
	AH	Rebuffe-Scrive et al., Int'l J. of Obesity, Vol. 15 (1991), p. 791-795, "Short Communication: Effect of testosterone on abdominal adipose tissue in men"
	AI	Ford et al., JAMA, Vol. 287 (2002), pp. 356-359, "Prevalence of the metabolic syndrome among U.S. adults"
	AJ	Parsons et al., Cancer Epidemiol. Biomarkers Prev., Vol. 14 (2005), pp. 2257-2260, "Serum testosterone and the risk of prostate cancer ..."
	AK	Thompson et al., N. Eng. J. Med., Vol. 349 (2003), pp. 215-224, "The influence of finasteride on the development of prostate cancer"
	AL	Laaksonen et al., Diabetes Care, Vol. 27 (2004), pp. 1036-1041, "Testosterone and sex hormone-binding globulin predict the metabolic syndrome and diabetes in middle-aged men"
	AM	Laaksonen et al., Eur. J. of Endocrinol., Vol. 149 (2003), pp. 601-608, "Sex hormones, inflammation and the metabolic syndrome: a population-based study"
	AN	Keating et al., J. of Clin. Oncology, Vol. 24 (2006), pp. 4448-4456, "Diabetes and cardiovascular disease during androgen deprivation therapy for prostate cancer"
↓	AO	Dhindsa et al., J. of Clin. Endocrinol. Metab., Vol. 89 (2004), pp. 5462-5468, "Frequent occurrence of hypogonadotropic hypogonadism in type 2 diabetes"

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/U.R./	AP	Shores et al., Arch. Intern. Med., Vol. 166 (2006), pp. 1660-1665, "Low serum testosterone and mortality in male veterans"
	AQ	Kaplan et al., J. of Urology, Vol. 176 (2006), pp. 1524-1528, "The age related decrease in testosterone is significantly exacerbated in obese men with the metabolic syndrome ..."
	AR	Pitteloud et al., Diabetes Care, Vol. 28 (2005), pp. 1636-1642, "Relationship between testosterone levels, insulin sensitivity, and mitochondrial function in men"
	AS	Belanger et al., Horm. Metab. Res., Vol. 34 (2002), pp., 737-745, "Adipose tissue intracrinology: Potential importance of local androgen/estrogen metabolism in the regulation of adiposity"
	AT	Liverman et al. (editors), Testosterone and Aging (2002), Institute of Medicine of the National Academies, The National Academies Press, Washington, DC, pp. 1-211
	AU	Marks et al., JAMA, Vol. 296 (2006), pp 2351-2361, "Effect of testosterone replacement therapy on prostate tissue in men with late-onset hypogonadism"
	AV	Uygur et al., Steroids, Vol. 63 (1998), pp. 208-213, "Effects of the 5alpha-reductase inhibitor finasteride on serum levels on gonadal, adrenal, and hypophyseal hormones and its clinical significance ..."
	AW	Bialek et al., Pol. J. Pharmacol., Vol. 56 (2004), pp. 509-518, "Neuroprotective role of testosterone in the nervous system"
	AX	Okun et al., Neurology, Vol. 62 (2004), pp. 411-413, "Plasma testosterone levels in Alzheimer and Parkinson diseases"
	AY	Tan et al., The Aging Male, Vol. 6 (2003), pp. 13-17, "A pilot study on the effects of testosterone in hypogonadal aging male patients with Alzheimer's disease"
	AZ	Moffat et al., Neurology, Vol. 62 (2004), pp. 188-193, "Free testosterone and risk for Alzheimer disease in older men"
	BA	Okun et al., Arch. Neurol., Vol. 59 (2002), pp. 1750-1753, "Beneficial effects of testosterone replacement for the nonmotor symptoms of Parkinson disease"
	BB	Roehrborn C, Andriole A, Nickel JC, Boyle P, Hofner K. Effect of the dual 5alpha-reductase inhibitor dutasteride on endocrine parameters and prostate volume. European Urology, Vol. 41 (2002), (1 Suppl, 1), 107. Poster included.
	BC	Rhoden et al., N. Eng. J. Med., Vol. 350 (2004) pp. 482-492, "Risks of testosterone-replacement therapy and recommendations for monitoring"
	BD	Kastelstein et al., Am. J. of Cardiology, Vol. 86 (2000), pp. 221-223, "Comparison of effects of Simvastatin versus Atorvastatin on high-density lipoprotein cholesterol and apolipoprotein A-1 Levels"

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/U.R./

BE

Crouse et al., Am. J. Cardiology, Vol. 83 (1999), pp. 1476-1477, "Effects of high doses of Simvastatin and Atorvastatin on high-density lipoprotein cholesterol and apolipoprotein A-1"

**BF**

Westerbacka et al., J. Clin. Endocrinol. Metab., Vol. 88 (2003), pp. 4924-4931, "Body fat distribution and cortisol metabolism in healthy men: Enhanced 5 $\beta$ -reductase and lower cortisol/cortisone metabolite ratios ..."

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Andrew et al., J. Clin. Endocrinol. Metab., Vol. 83 (1998), pp. 1806-1809, "Obesity and gender influence cortisol secretion and metabolism in man"

BH

Amory et al., J. Clin. Endocrinol. Metab., Vol. 90 (2005), pp. 2610-2617, "Oral testosterone in oil plus dutasteride in men: A pharmacokinetic study"

BI

Leibowitz et al., Am. Society of Clinical Oncology, Abstract 1617 (2003), "Primary hormonal therapy with finasteride and bicalutamide in advance prostate cancer (CaP)"

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